

Appl. No. : 09/853,080  
Filed : May 9, 2001

## REMARKS

### Status of Claims

Claims 29, 34 and 35 have been amended. Support for the amendments can be found in the Specification as filed, for example, pages 11 lines 19-20, 17 lines 10-20; and 21 lines 23-24. The specific amino acid location of the Factor VIII C domain was described in Foster et al. 1989, cited on page 42 line 8 of the Specification. Therefore, no new matter has been introduced by these amendments. The following addresses the substance of the Office Action.

### Compliance with 35 USC §102(b)

The Examiner has rejected Claims 29 and 30 under 35 USC §102(b) as being allegedly anticipated by USP 4965199. More specifically, the Examiner alleges that the claims 29 and 30 read on the full-length Factor VIII as taught in the cited patent. Applicant respectfully disagrees.

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. ...There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

Claims 29 and 30 as well as Claims 34 and 35 as currently amended are drawn to specific antigenic fragments of Factor VIII polypeptide and therefore do not read on the full-length Factor VIII of USP 4965199. For the above reason, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 102, and allowance of the pending application.

### Compliance with 35 USC §112, second paragraph.

The Examiner has rejected Claims 34-38 under 35 USC §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More specifically, Claim 34 was rejected for reciting the term "sequence C of Factor VIII". Applicant has amended Claim 34 to now recite "factor VIII C domain, wherein said Factor VIII C domain is between amino acids 2020 and 2332 of SEQ ID NO: 49", which is supported in the Specification as filed on page 1, lines 23-24 and page 42:8. Claim 35 was rejected for reciting in subsection (h) epitopes (a) through (i), when the claim is

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only up to letter (h), and in subsection (m) reciting the epitope (m). Claim 35 was amended accordingly. As a result, Claims 34 and 35 are now definite, and their rejection should be withdrawn.

### CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. Any claim amendments which are not specifically discussed in the above remarks are made in order to improve the clarity of claim language, to correct grammatical mistakes or ambiguities, and to otherwise improve the capacity of the claims to particularly and distinctly point out the invention to those of skill in the art. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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